

REMARKS

The specification is amended so that the ring refers to drawing reference number 56b. This typographic correction fully addresses the objection to the drawings.

Claim 1 is amended to incorporate the subject matter of original claims 2 and 4. Claim 1 is further amended to replace “anatomosed to” with “disposed for anastomosis with” in order to avoid any suggestion that the claimed article is one already connected with an artery or vein. Similarly, we have revised the claim language to recite “a cannula assembly connectable to a dialyzer” rather than connected. Finally, the claim is amended to correct mistakes in grammar.

Claim 3 is amended to correct spelling.

Claims 7 and 10 are each amended to depend on claim 1, and likewise claims 8 and 11 amended to depend on claim 3.

The remaining claims are cancelled as moot in view of the above amendments.

New independent claim 13 contains the subject matter of amended claim 1 with the added limitation that “wherein the device is disposed so that, when in use, the peripheral wall passes through the skin, and the shutters are disposed at least partially outside the plane of the skin” as supported by, *e.g.*, Fig. 9.

The present amendment adds no new matter to the application.

The Rejections

The Examiner rejects claims 1-12 under 35 U.S.C. § 103(a) as unpatentable over Colone (U.S. Patent No. 4,822,341) in view of Kawamura (EP 1,013,293) [hereinafter “Kawamura ‘293”].

In view of the present amendment, Applicants respectfully traverse the present rejections and request reconsideration and allowance of the remaining claims for the

following reasons.

The Invention

The present invention relates to a blood access device for hemodialysis that is of a no-needle type. With the invention, the artery or vein will be in communication with the dialyzer without leakage of blood, so that hemodialysis can be done without a caregiver. The device of the present invention provides these features with a relatively simple structure, enabling manufacture at low cost, and ease of handling.

Applicant's Arguments

Regarding the rejection of over Colone in view of Kawamura '293, the references fail to teach the elements of the present claims, so that no *prima facie* case has been made under § 103. Colone has the tubular connectors 36 and 38 (to which access tubes 46 and 80 are connected) located within the body of the patient (Fig. 4; *see also* col. 7, lines 52-66).

Colone fails to teach "a pair of cannulas, one end of each of the cannulas being provided with an adapter for mounting the cannula to the body, the adapter being provided with a locking member for preventing the cannula from being removed" as recited in each of the independent claims. As seen, Colone has a completely different way of interfacing the device with the dialyzer. Regarding Kawamura '293, the reference also is completely different in this regard: the leading end of each of the cannulas must be inserted into the artery or vein of the patient (Fig. 2). The claimed locking cannula assembly of this invention, in conjunction with the other elements of the claims, goes to the essential features of the invention, namely providing a no-needle blood access device with a simple structure for ease manufacture and low cost. The claimed features distinguishes this invention from the prior art. Because the references fail to teach the elements of the independent claims as currently amended,

Applicants respectfully request reconsideration and withdrawal of the rejections under § 103.

Further regarding Colone, the reference has the horizontal portion 22 (which is a valve member) entirely within the body of the patient, with a dual lumen access tube 78 leading outside the body. Thus, Colone fails to teach, or even suggest that “the device is disposed so that, when in use, the peripheral wall passes through the skin, and the shutters are disposed at least partially outside the skin” as recited in new independent claim 13. For this reason, Applicants further traverse any rejection of new claim 13 over Colone.

Conclusion

For all of the above reasons, claims 1, 3, 7, 8, 10, 11, and 13 are now in condition for allowance. Therefore, Applicants respectfully request reconsideration of the application and withdrawal of the rejections, and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below signed attorney for the Applicants.

Respectfully submitted,

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